1. INTRODUCTION

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) created a new outpatient drug benefit for Medicare beneficiaries, designated as Medicare Part D. The MMA relies on competition among private drug plans (PDPs) and Medicare Advantage (MA) plans as the basis for offering the Part D benefit. The plans are at risk for the cost of the benefit (although the risk is tempered through reinsurance and risk sharing mechanisms), and thus plans have a significant incentive to control costs. The MMA expects private plans to provide a drug benefit of an acceptable quality to beneficiaries, so includes several provisions to ensure that beneficiaries maintain access to needed drugs.

In general, plans are expected to offer beneficiaries all needed drugs, and the standard benefit presented in the statute would cover those drugs with a fixed 25 percent coinsurance. But the law does not require plans to use a predetermined drug classification system, formulary, or cost sharing. Instead, plans have flexibility to limit the drugs they cover through a formulary and to provide incentives to use preferred drugs through tiered cost sharing. It is likely that most plans will offer a variety of packages that cover different drugs at different levels of cost sharing.

Plans can use formularies – lists of preferred or covered drugs -- to control costs by steering enrollees to use lower-cost drugs. In addition, plans can negotiate manufacturer rebates on a particular drug in exchange for demonstrating the ability to shift consumers to that drug and away from the drug's competitors. The use of formularies has grown dramatically in the private sector. According the Kaiser/HRET survey of employer health benefits, 71 percent of employees in 2003 were enrolled in a plan that used formularies, compared to just 43 percent of employees in 2000.[1]

Formularies can be either "closed" – in which there is no coverage at all for non-formulary drugs – or "open" – in which non-formulary drugs are covered, but plans use incentives to encourage their enrollees to use the preferred drugs on the formulary. Most private sector plans have responded to their enrollees' desire for more choice by creating open formularies.[2] There is some evidence that in Medicare+Choice plans, closed formularies have been more common. In 2002, about 37 percent of M+C enrollees were in a plan with a closed formulary.[3] The Veterans Health Administration began using a closed formulary for some drug classes in 1997.

To give enrollees clear incentives to follow the formulary or use cheaper drugs, plans often use tiered cost sharing. A common incentive structure used with open formularies (accounting for 63 percent of covered workers in 2003) [4] is a three-tier copay. These

[1] Kaiser Family Foundation and Health Research and Education Trust, *Employer Health Benefits: 2003 Annual Survey.* Menlo Park and Chicago, 2003.
[2] *Takeda Prescription Drug Benefit Cost and Plan Design Survey Report*, 2001 edition. Pharmacy Benefit Management Institute, Inc., 2002.
[3] Achman, Lori, and Marsha Gold, *Trends in Medicare+Choice Benefits and Premiums, 1999-2002*, The Commonwealth Fund, November 2002.
[4] Kaiser Family Foundation and Health Research and Education Trust, *Employer Health Benefits: 2003 Annual Survey.* Menlo Park and Chicago, 2003.

employees pay a low copay (e.g., $9) for generics, more (e.g. $19) for "preferred," on-formulary brand name drugs, and the most (e.g. $29) for "non-preferred," off-formulary drugs. Closed formularies may also use tiered cost-sharing for covered drugs, for example, by creating a different copay for brands vs. generics.

Other incentives that plans can use to steer enrollees to use drugs on the formulary or on preferred tiers of that formulary include the following:

Prior authorization: The pharmacist or physician must obtain authorization from the plan before an enrollee can fill a prescription for a drug.
Step therapy: Enrollees must try a less expensive drug before receiving coverage for a more expensive drug. For example, they must try ibuprofen first, then naproxen sodium, and only if neither of those works would coverage be approved for a Cox-2 inhibitor.
Therapeutic substitution: The pharmacist contacts the prescribing physician when an enrollee tries to fill a prescription for a non-formulary drug, and asks to switch the enrollee to an on-formulary drug.
Patient and prescriber education: Some plans contact patients and prescribers to let them know a lower-cost drug is available.

The Secretary has statutory authority to disallow arrangements that discriminate against certain beneficiaries. Through regulations and regulatory guidance, HHS has developed policies around formularies, cost sharing, and other utilization management practices to enforce this statutory provision. This oversight could be particularly important if plans use design elements as ways to avoid enrolling high-risk beneficiaries, or if beneficiaries can not effectively shop in this market.

A number of issues may arise with regard to formularies and benefit design under the new benefit. Plans face competing incentives toward offering broader or more restrictive formularies, within the bounds of the regulatory provisions that a formulary must meet. Broad formularies would ensure better access to many drugs and potentially make the plan more attractive to potential enrollees. But more restrictive formularies may enhance plans' leverage in obtaining price concessions from manufacturers, thus making it easier for them to balance their books and to offer an attractive premium in the competitive marketplace. Restrictive formularies, however, increase the chance of disputes with beneficiaries and place more reliance on an effective exceptions and appeals process. Plans offering broad formularies may rely more on cost management tools such as sharply tiered cost sharing, step therapy, or prior authorization to limit the use of more expensive drugs.

Some observers speculate that plans may prefer to offer broad formularies in the first years of the benefit in order to attract enrollment and survive in a marketplace that may have a large number of players. But those that achieve strong market shares may turn to more restrictive formularies or more tiered cost sharing in later years to control costs.

In preparation for implementation of the pharmacy benefit, ASPE asked a team from NORC and Georgetown University to research current formularies and classification schemes, and to model how beneficiaries might react to formularies under the Part D benefit. The goal was to understand better current formulary practice in the private sector, with an eye toward learning whether the rules developed to enforce the MMA are generally consistent with current practice. The project further aims to understand the range of formularies that might be permissible under the MMA rules and to shed light on the potential degree to which beneficiaries might need to switch medications as a result of allowable formularies. Still, it is important to recognize that, although the findings of this project are based roughly on a set of private-sector formularies, they are not based on formularies that may be offered by Medicare Part D plans. Thus, they provide a framework for thinking about the role formularies may play in Part D but cannot project actual behavior under the new Medicare benefit.